

**Remarks**

The Office Action mailed May 27, 2005 has been reviewed and the following remarks have been made in consequence thereof.

Claims 1-16 are now pending in this application. Claims 1-5, 7-11, and 13-16 are rejected. Claims 6 and 12 are objected to. Claims 1, 4, 6, 7, 10, 12, and 13 have been amended. No new matter has been added. A fee calculation sheet is submitted herewith for the independent Claims 6 and 12.

The rejection of Claims 1, 2, 7, 8, 13, and 16 under 35 U.S.C. § 102(b) as being anticipated by Williams et al. (U.S. Patent No. 5,485,494) is respectfully traversed.

Williams et al. describe a system in which an mA command is calculated at a process block (153) by using an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$  (column 5, lines 28-30). In the equation, mA is a tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle (column 5, lines 11, 12, 19, 20, column 4, lines 21-25, 38-40).

Claim 1 recites an X-ray controlling method for an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising the steps of "setting an upper limit of an X-ray exposure dose to the subject to be imaged; and modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating the tube current includes modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose."

Williams et al. do not describe or suggest an X-ray controlling method as recited in Claim 1. Specifically, Williams et al. do not describe or suggest modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube

current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Accordingly, Williams et al. do not describe or suggest modifying the tube current based upon a ratio as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Williams et al.

Claim 2 depends from independent Claim 1. When the recitations of Claim 2 are considered in combination with the recitations of Claim 1, Applicants submit that Claim 2 likewise is patentable over Williams et al.

Claim 7 recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a setting device for setting an upper limit of an X-ray exposure dose to the subject to be imaged; and a modulating device for modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose.”

Williams et al. do not describe or suggest an X-ray imaging apparatus as recited in Claim 7. Specifically, Williams et al. do not describe or suggest the modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where  $\text{mA}$  is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Accordingly, Williams et al. do not describe or suggest the modulating device configured to modulate the tube current based upon a ratio as recited in Claim 7. For the reasons set forth above, Claim 7 is submitted to be patentable over Williams et al.

Claim 8 depends from independent Claim 7. When the recitations of Claim 8 are considered in combination with the recitations of Claim 17, Applicants submit that Claim 8 likewise is patentable over Williams et al.

Claim 13 recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a calculating device for calculating a historical X-ray exposure dose value of an X-ray exposure dose to the subject to be imaged, wherein said calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value; and a display device for displaying the historical exposure dose value.”

Williams et al. do not describe or suggest an X-ray imaging apparatus as recited in Claim 13. Specifically, Williams et al. do not describe or suggest the calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Accordingly, Williams et al. do not describe or suggest the calculating device configured to change a tube current based upon a ratio as recited in Claim 13. For the reasons set forth above, Claim 13 is submitted to be patentable over Williams et al.

Claim 16 depends from independent Claim 13. When the recitations of Claim 16 are considered in combination with the recitations of Claim 13, Applicants submit that Claim 16 likewise is patentable over Williams et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 102 rejection of Claims 1, 2, 7, 8, 13, and 16 be withdrawn.

The rejection of Claims 3 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Williams et al., and further in view of Suzuki et al. (U.S. Patent No. 6,590,953) is respectfully traversed.

Williams et al. is described above. Suzuki et al. describe an X-ray CT scanner in which a spiral CT method can be implemented. The spiral CT method has enabled a substantial reduction in a time required to perform a three-dimensional CT imaging by continuously rotating an X-ray tube and an X-ray detector around a subject while moving a table on which the subject is placed, collecting cross-sectional image data in multiple layers over a wide range and reconstructing the data into an image (column 1, lines 31-37).

Claim 3 depends indirectly from independent Claim 1 which recites an X-ray controlling method for an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising the steps of “setting an upper limit of an X-ray exposure dose to the subject to be imaged; and modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating the tube current includes modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose.”

Neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest an X-ray controlling method as recited in Claim 1. Specifically, neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Suzuki et al. describe continuously rotating an X-ray tube and an X-ray detector around a subject while moving a table on which the subject is placed. Accordingly, neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest modifying the tube current based upon a ratio as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Williams et al. and further in view of Suzuki et al.

When the recitations of Claim 3 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 3 likewise is patentable over Williams et al. and further in view of Suzuki et al.

Claim 9 depends indirectly from independent Claim 7 which recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a setting device for setting an upper limit of an X-ray exposure dose to the subject to be imaged; and a modulating device for modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose.”

Neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest an X-ray imaging apparatus as recited in Claim 7. Specifically, neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest the modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Suzuki et al. describe continuously rotating an X-ray tube and an X-ray detector around a subject while moving a table on which the subject is placed. Accordingly, neither Williams et al. nor Suzuki et al., considered alone or in combination, describe or suggest the modulating device configured to modulate the tube current based upon a ratio as recited in Claim 7. For the reasons set forth above, Claim 7 is submitted to be patentable over Williams et al. and further in view of Suzuki et al.

When the recitations of Claim 9 are considered in combination with the recitations of Claim 7, Applicants submit that dependent Claim 9 likewise is patentable over Williams et al. and further in view of Suzuki et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 3 and 9 be withdrawn.

The rejection of Claims 4, 5, 10, and 11 under 35 U.S.C. § 103(a) as being unpatentable over Williams et al., and further in view of Eisenberg et al. (U.S. patent Application Publication No. 2003/0128801 A1) is respectfully traversed.

Williams et al. is described above. Eisenberg et al. describe a planning system (44). A plurality of dose control parameters are transmitted to the planning system to adjust protocol x-ray dose/mAs levels to achieve a desired image quality with minimum dosage to a patient (paragraph 112). A dosage subsection of the planning system predicts dosages based upon protocol selected and computes integral dosages based upon a plurality of interconnected protocols for volume computed tomography (VCT), gated VCT, and angio-graphic VCT, tri-phasic VCT, positron emission tomography (PET) and single photon emission computed tomography (SPECT) imaging (paragraph 112).

Claims 4 and 5, depend indirectly from independent Claim 1 which recites an X-ray controlling method for an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising the steps of “setting an upper limit of an X-ray exposure dose to the subject to be imaged; and modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating the tube current includes modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose.”

Neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest an X-ray controlling method as recited in Claim 1. Specifically, neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest modifying the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180

degrees of gantry angle. Eisenberg et al. describe predicting dosages based upon a protocol selected and computing integral dosages based upon a plurality of interconnected protocols for volume computed tomography (VCT), gated VCT, and angio-graphic VCT, tri-phasic VCT, positron emission tomography (PET) and single photon emission computed tomography (SPECT) imaging. Accordingly, neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest modifying the tube current based upon a ratio as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Williams et al. and further in view of Eisenberg et al.

When the recitations of Claims 4 and 5 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 4 and 5 likewise are patentable over Williams et al. and further in view of Eisenberg et al.

Claims 10 and 11 depend indirectly from independent Claim 7 which recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a setting device for setting an upper limit of an X-ray exposure dose to the subject to be imaged; and a modulating device for modulating a tube current of the X-ray tube so that the exposure dose does not exceed the upper limit, wherein said modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose.”

Neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest an X-ray imaging apparatus as recited in Claim 7. Specifically, neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest the modulating device configured to modulate the tube current based upon a ratio of the upper limit and a predicted value of the exposure dose. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Eisenberg et al. describe predicting dosages based upon a protocol selected and computing integral

dosages based upon a plurality of interconnected protocols for volume computed tomography (VCT), gated VCT, and angio-graphic VCT, tri-phasic VCT, positron emission tomography (PET) and single photon emission computed tomography (SPECT) imaging. Accordingly, neither Williams et al. nor Eisenberg et al., considered alone or in combination, describe or suggest the modulating device configured to modulate the tube current based upon a ratio as recited in Claim 7. For the reasons set forth above, Claim 7 is submitted to be patentable over Williams et al. nor Eisenberg et al.

When the recitations of Claims 10 and 11 are considered in combination with the recitations of Claim 7, Applicants submit that dependent Claims 10 and 11 likewise are patentable over Williams et al. nor Eisenberg et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 4, 5, 10, and 11 be withdrawn.

The rejection of Claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Williams et al., and further in view of Tsoulfanidis (*Measurement and Detection of Radiation*, pp. 567-569, Taylor and Francis, second edition (1995)) is respectfully traversed.

Williams et al. is described above. Tsoulfanidis describes a system in which radiation exposure limits are set at such levels that nonstochastic biological effects do not occur (page 567). In the system, radiation exposure limits are set at such levels that stochastic effects are minimized and become acceptable in view of the benefits derived from an exposure (page 567).

Claim 14 depends from independent Claim 13 which recites Claim 13 recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a calculating device for calculating a historical X-ray exposure dose value of an X-ray exposure dose to the subject to be imaged, wherein said calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value; and a display device for displaying the historical exposure dose value.”



Neither Williams et al. nor Tsoulfanidis, considered alone or in combination, describe or suggest an X-ray imaging apparatus as recited in Claim 13. Specifically, neither Williams et al. nor Tsoulfanidis, considered alone or in combination, describe or suggest the calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Tsoulfanidis describes setting radiation exposure limits at such levels that nonstochastic biological effects do not occur. Accordingly, neither Williams et al. nor Tsoulfanidis, considered alone or in combination, describe or suggest the calculating device configured to change a tube current based upon a ratio as recited in Claim 13. For the reasons set forth above, Claim 13 is submitted to be patentable over Williams et al. and further in view of Tsoulfanidis.

When the recitations of Claim 14 are considered in combination with the recitations of Claim 13, Applicants submit that dependent Claim 14 likewise is patentable over Williams et al. and further in view of Tsoulfanidis.

For at least the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 14 be withdrawn.

The rejection of Claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Williams et al. and Tsoulfanidis, and further in view of Herzog (U.S. Patent No. 6,241,668) is respectfully traversed.

Williams et al. and Tsoulfanidis are described above. Herzog describes a plurality of work stations (5-8) that are connected to an image communication network (9) for communication and distribution of a plurality of created images (column 2, lines 33-35). The images produced in a plurality of modalities (1-4) and the images processed in the work stations thus can be stored in a central image storage and image archiving system (10) or can be forwarded to other work stations (column 2, lines 35-39).

Claim 15 depends indirectly from independent Claim 13 which recites Claim 13 recites an X-ray imaging apparatus for projecting X-rays from an X-ray tube onto a subject to be imaged and detecting transmitted X-rays, and producing an image based on detected X-ray signals, comprising “a calculating device for calculating a historical X-ray exposure dose value of an X-ray exposure dose to the subject to be imaged, wherein said calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value; and a display device for displaying the historical exposure dose value.”

None of Williams et al., Tsoulfanidis, or Herzog, considered alone or in combination, describe or suggest an X-ray imaging apparatus as recited in Claim 13. Specifically, none of Williams et al., Tsoulfanidis, or Herzog, considered alone or in combination, describe or suggest the calculating device configured to change a tube current based upon a ratio of a limit of the exposure dose and the historical exposure dose value. Rather, Williams et al. describe calculating a tube current based upon an equation,  $\text{mA command} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Tsoulfanidis describes setting radiation exposure limits at such levels that nonstochastic biological effects do not occur. Herzog describes forwarding images produced in a plurality of modalities and images processed in a plurality of work stations to other work stations via a network. Accordingly, none of Williams et al., Tsoulfanidis, or Herzog, considered alone or in combination, describe or suggest the calculating device configured to change a tube current based upon a ratio as recited in Claim 13. For the reasons set forth above, Claim 13 is submitted to be patentable over Williams et al. and Tsoulfanidis, and further in view of Herzog.

When the recitations of Claim 15 are considered in combination with the recitations of Claim 13, Applicants submit that dependent Claim 15 likewise is patentable over Williams et al. and Tsoulfanidis, and further in view of Herzog.

For at least the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 15 be withdrawn.

Moreover, Applicants respectfully submit that the Section 103 rejections of Claims 3, 4, 5, 9, 10, 11, 14, and 15 are not proper rejections. As is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. None of Williams et al., Suzuki et al., or Eisenberg et al., Tsoulfanidis, or Herzog, considered alone or in combination, describe or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Williams et al. with Suzuki et al., or Eisenberg et al., Tsoulfanidis, or Herzog because there is no motivation to combine the references suggested in the cited art itself.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicants' disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejections are based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Williams et al. teach calculating a tube current based upon an equation,  $\text{mA}_{\text{command}} = \text{mA}_{\text{max}} (1 - (\alpha * \text{basis table value}))$ , where mA is the tube current,  $\text{mA}_{\text{max}}$  is a precalculated maximum dose,  $\alpha$  is a precalculated modulation

index by which the maximum dose is modulated, and basis value table is a table that stores a modulation waveform for 180 degrees of gantry angle. Suzuki et al. teach continuously rotating an X-ray tube and an X-ray detector around a subject while moving a table on which the subject is placed. Eisenberg et al. teach predicting dosages based upon a protocol selected and computing integral dosages based upon a plurality of interconnected protocols for volume computed tomography (VCT), gated VCT, and angio-graphic VCT, tri-phasic VCT, positron emission tomography (PET) and single photon emission computed tomography (SPECT) imaging. Tsoulfanidis teaches setting radiation exposure limits at such levels that nonstochastic biological effects do not occur. Herzog teaches forwarding images produced in a plurality of modalities and images processed in a plurality of work stations to other work stations via a network. Since there is no teaching nor suggestion in the cited art for the combination, the Section 103 rejections appear to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicants request that the Section 103 rejections of Claims 3, 4, 5, 9, 10, 11, 14, and 15 be withdrawn.

For at least the reasons set forth above, Applicants respectfully request that the rejections of Claims 3, 4, 5, 9, 10, 11, 14, and 15 under 35 U.S.C. 103(a) be withdrawn.

Claims 6 and 12 have been indicated to contain allowable subject matter if rewritten in independent form to include all of the limitations of the respective base claims and any respective intervening claims. Claim 6 has been amended to include the recitations of independent Claim 1 and intervening Claims 2, 4, and 5. Claim 12 has been amended to include the recitations of independent Claim 7 and intervening Claims 8, 10, and 11. Accordingly, Applicants respectfully submit that Claims 6 and 12 are in condition for allowance.



In view of the foregoing amendment and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Patrick W. Rasche".

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